

### **REMARKS**

Claims 1-84 are pending in the above-identified application. Claims 16-77 have been cancelled without prejudice as being drawn to a non-elected invention. Applicant reserves the right to pursue these withdrawn claims in a later filed application claiming the benefit of priority to the above-identified application. Independent claims 1, 7 and 78 have been amended above. Upon entry of the amendments, claims 1-15 and 78-84 will be pending and under examination.

Support for the amendments can be found throughout the application. Specifically, support for the amendment to recite that a label monomer is bound to a nucleotide within a nucleic acid molecule in a 1:1 correspondence can be found described in the application, for example, at page 6, line 14 through page 7, line 9. Accordingly, the amendments do not raise an issue of new matter and entry thereof is respectfully requested.

Moreover, the amendment reciting that label monomers of the claimed unique labels are attached in a 1:1 correspondence with a nucleotide does not raise new issues for consideration by the Office because it merely recites the specific language of the term "bound" as it is defined in the specification and as Applicant has argued of record. Further, because the amendment merely incorporates the definitional language of a claim term, it neither broadens nor narrows the scope of the claims as they were pending prior to entry of the above amendments. Accordingly, the amendment places the application in condition for allowance without raising new issues for consideration and without changing the scope of the claims as they were pending prior to the above amendments. Accordingly, entry and consideration thereof is respectfully requested.

Applicant wishes to thank Examiner Chunduru for the telephonic interview extended to Applicant's representative on September 23, 2003, in which the definition of the term "bound" was discussed in light of the rejections of record over the cited art. The Examiner indicated that removal of these rejections would be viewed favorably if the claims were amended to recite the features of the term "bound" as it is defined in the specification. The claims have

been amended above to replace the term bound with its definition in the specification. Therefore, the above amendments and remarks that follow are believed by Applicant to substantially conform to the understanding reached in the telephonic interview of September 23, 2003.

### **Rejections Under 34 U.S.C. §102**

Claims 1-6 stand rejected under 35 U.S.C. §102 (b) as allegedly anticipated by the PCT application to Chandler (WO 99/52708). The office action maintains that Chandler describes microparticles with multiple fluorescent signals having a unique population of labels with one or more unique labels bound to DNA (microparticles). The office action acknowledges Applicant's argument that Chandler does not teach a label monomer attached to a nucleotide in a 1:1 correspondence, as is defined by the term "bound" in the specification but asserts that limitations from the specification are not read into the claims.

The law is clear with respect to claim construction. The meaning of a term is to be given its ordinary meaning or the meaning provided to it when defined in the specification. In its decisions in *Markman* and *Vitronics*, the Federal Circuit stated:

[I]t is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning. The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.

*Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (citing *Markman v. Westview Instr.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (*in banc*), *aff'd*, 517 U.S. 370 (1996)); accord *Abbott Laboratories v. Novopharm Ltd.*, 323 F.3d 1324, 1330, (Fed. Cir. 2003) (court limiting meaning of a term to the narrower definition defined in the specification).

Claims 1-6 recite a diverse population of unique labels where each unique labels is bound to a nucleic acid molecule. The term "bound" is defined in the specification, for example, at page 6, lines 14-17, as meaning that a label monomer is attached to a nucleotide in a

1:1 correspondence. Because the term "bound" has a defined meaning set forth in the specification, it is required by law to be given that definition. *Vitronic*, 90 F.3d at 1582; *Markman* 52 F.3d at 979; *Abbott Laboratories* 323 F.3d at 1330.

Chandler does not describe unique labels bound in a 1:1 correspondence to a nucleotide. Instead, Chandler describes the use of dyed core microparticles and the use of carrier microparticles to which nanoparticles having a plurality of dyes are attached (see page 6, lines 5-8). Chandler describes methods for labeling where microparticles are stained with dyes in bulk (see page 13, lines 24-37), which results in an undetermined plurality of label monomers adsorbed onto the particles and a variable ratio label monomer to nucleotide. Because Chandler does not describe a 1:1 attachment of label monomer to nucleotide within the nucleic acids of the microparticle, Chandler cannot anticipate the claimed invention.

While not conceding that Chandler anticipates the claimed invention, Applicant has amended the claims above to recite that the claimed unique labels are bound to a nucleic acid by attachment of a label monomer in a 1:1 correspondence with a nucleotide. The meaning of the term "bound" as it is defined in the specification is now expressly recited in the claims. Accordingly, the rejection over Chandler is moot and Applicant respectfully requests that this ground of rejection be withdrawn.

Claims 1-13 stand newly rejected under 35 U.S.C. § 102 (b) as allegedly anticipated by U.S. Patent No. 4,824,775 to Dattagupta et al. The office action alleges that Dattagupta et al. describe multiple fluorescent signals bound to a nucleic acid that meet the limitations of claims 1-13 of the subject application. Specific passages are cited in support of this assertion.

Dattagupta et al. does not anticipate the claimed invention because it fails to describe a population of thirty or more unique labels unique labels bound to a nucleic acid by attachment of a label monomer in a 1:1 correspondence with a nucleotide as is claimed by the invention.

Instead, Dattagupta et al. appears to describe a cell labeled with an antibody attached to a nucleic acid. The nucleic acid can contain multiple labels to increase the sensitivity of cell separation (abstract). However, in contrast to that asserted in the office action, the labels described by Dattagupta do not constitute a population of thirty or more unique labels. First, Dattagupta et al. describe at column 3, lines 4-16, that the nucleic acid described therein is heavily labeled with a fluorescent molecule and at column 1, line 64 through column 2, line 18, that there "maximum number of fluorophores available per molecule is . . . fixed." Moreover, only the three fluorophores fluorescein, rhodamine and phycobiliproteins are listed. Second, Dattagupta et al. describe at column 4, lines 26-31, that the DNA is labeled so multiple copies of the label will be attached to the DNA. Finally, at column 4, lines 61-64, Dattagupta et al. describes that the length of the DNA can be adjusted to increase the number of fluorophores incorporated into the molecule. Increasing the number of copies of a fluorophore is described as being an improvement for cell sorting aimed at increasing the sensitivity of the assay. Accordingly, Dattagupta et al. does not describe a population of about thirty or more unique labels.

Because Dattagupta et al. fails to describe every element recited in the claims, it cannot anticipate the claimed invention. Accordingly, Applicant respectfully requests that this ground of rejection be withdrawn.

#### **Rejections Under 35 U.S.C. § 103**

Claims 7-15 and 78-84 stand rejected under 35 U.S.C. §103(a) as allegedly obvious over Chandler (WO 99/52708) in view of Chandler et al. (WO 99/37814). The office action maintains that Chandler ('708) describes a unique or distinct population of labels. Chandler ('708) does not describe labeled probes attached to uniquely labeled microparticles. The office action alleges that Chandler et al. ('814) describe microparticles attached with oligonucleotide probes and that it would have been obvious to a person of ordinary skill in the art to combine the labeled microparticles as taught by Chandler ('708) with the labeled probes as taught by Chandler et al. ('814) to obtain the claimed invention. The office action acknowledges Applicant's argument that the cited references do not teach or suggest a label monomer attached

to a nucleotide in a 1:1 correspondence, as is defined by the term "bound" in the specification but asserts that limitations from the specification cannot read into the claims.

Claims 7-15 of the subject application recite a diverse population of uniquely labeled probes having about thirty or more target specific nucleic acid probes each attached to a unique label bound to a nucleic acid where label monomers of the unique labels are attached to nucleotides in a 1:1 correspondence. Claims 78-84 recite a nucleic acid labeling kit having a set of genedigits, a set of anti-genedigits and a unique set of labels bound to a nucleic acid by attachment of label monomers of said unique labels to nucleotides in a 1:1 correspondence.

Because the term "bound" has a defined meaning set forth in the specification, it is required by law to be given that definition. *Vitronic*, 90 F.3d at 1582; *Markman* 52 F.3d at 979; *Abbott Laboratories* 323 F.3d at 1330. As described previously with reference to the express definition of the term "bound," the claims are directed to attachment of a label monomer to a nucleotide in a 1:1 correspondence. Neither Chandler ('708) nor Chandler et al. ('814) teach or suggest a unique label bound to a nucleic acid where a label monomer is attached to a nucleotide in a 1:1 correspondence as taught in the subject application.

Nevertheless, while not conceding that the cited references render the claimed invention obvious, Applicant has amended the claims above to recite that the claimed unique labels are bound to a nucleic acid by attachment of a label monomer in a 1:1 correspondence with a nucleotide. The meaning of the term "bound" as it is defined in the specification is now expressly recited in the claims. Accordingly, the rejection over Chandler ('708) in view of Chandler et al. ('814) is moot and Applicant respectfully requests that this ground of rejection be withdrawn.

### **CONCLUSION**

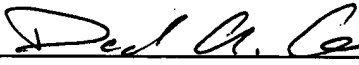
In light of the amendments and remarks herein, Applicant submits that the claims are in condition for allowance and respectfully requests a notice to this effect. Should the

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Examiner have any questions related to this application, she is invited to contact the undersigned attorney.

Respectfully submitted,

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